

### REMARKS

Claims 16, 19-25, and 30-36 are presently pending. Newly presented claims 32-36 have been deemed withdrawn. Claim 32 has been amended herein to correct a typographical error - the amendment does not introduce any new matter.

#### **The Claims are Enabled Within the Meaning of 35 U.S.C. § 112, first paragraph**

Claims 16 and 19-25 stand rejected as allegedly failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph. Applicants respectfully traverse this rejection.

Applicants respectfully assert that maintaining the enablement rejection is improper in this case. It is unarguable that the specification enables the skilled artisan to physically practice the step of genetically engineering a *Vanilla planifolia* to overproduce an enzyme having the amino acid sequence of SEQ ID NO: 2, or an enzyme encoded by SEQ ID NO:1. Although the claim as such is free of prior art, rather than allowing the claims, the Office Action has rejected them by apparently interpreting that preamble of the claim to limit the claim.

Interpreting the claim to require the absolute increase of vanillin production is improper here. As the MPEP states:

“The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use “can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim.” *Corning Glass Works*, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) (“where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation”). . . .”

MPEP 2111.02

Here, the claim does not breathe life and meaning into the claims, rather, the steps of genetically engineering the *V. planifolia* provide the necessary limitations of the claimed invention. Notwithstanding the subjective doubt and the references the Office Action has provided to allegedly evidence that overexpressing a rate-limiting enzyme in the biosynthesis of vanillin in *Vanilla planifolia* **might not** be successful, the skilled artisan would be enabled to practice the claims. Even if some experimentation is required to find those overexpressing mutants that have enhanced vanillin production; it is certainly not undue experimentation, it is at most highly routine. The question is whether the skilled artisan would be enabled to practice the claim limitations, and here, the answer is "Of course they would be."

Again as the MPEP states, the evidence of enablement provided by applicant need not be conclusive but merely convincing to one skilled in the art. *MPEP 2164.05* Based on the teachings of the specification and the knowledge in the art, embodied in part by the references provided by the Applicant, the skilled artisan would be convinced that overexpressing the chain-shortening enzymes, e.g. p-hydroxybenzaldehyde synthase, would lead to enhanced vanillin biosynthesis. Again, notwithstanding any subjective doubts, or speculation (e.g. Walton) as to why vanillin biosynthesis would not be susceptible to manipulation, the skilled artisan would be convinced that the carbon in that pathway could in fact be shunted to a desired end-product, e.g. vanillin. The Office Action argues that fact that the submitted references do not directly address the problem limits their potential to convince the skilled artisan. Applicants respectfully submit that that standard is far too harsh. If that were the operative standard, there would be virtually no advancement in science, and no law of obviousness. To the contrary, Applicants respectfully submit that the art is completely analogous and would have been meaningful to a skilled artisan confronting the problem the inventors did - i.e. how to improve throughput in a biosynthetic pathway in *V. planifolia*. Because the precise problem had not been previously faced, they would have looked to references concerning success in other pathways and other plants. Here, the submitted references teach other pathways involving carbon compounds in other plants - they are not so far afield. Greater scientific discoveries have been triggered from observations that were not nearly so on point.

Applicants respectfully request reconsideration of the enablement requirement. Given the narrow scope of the claim, and the specific sequences provided, it would be trivial to

genetically engineer the *V. planifolia* to overexpress the enzyme, and there would no need for any *undue* experimentation to determine if vanillin is overexpressed. Thus the claims are fully enabled. The preamble should not be used to limit the claim where the invention clearly provides steps for overproducing what the inventors claim is a rate-limiting enzyme in the biosynthetic pathway to vanillin.

### **Claims 32-36 Should Not be Withdrawn**

Previously present claims 32-36 (newly presented in the response to the last Office Action) stand withdrawn as allegedly not drawn to the elected group on which an Office Action on the merits has been received. Applicants respectfully request reconsideration of the withdrawal. In the alternative, if the arguments above are not found persuasive, Applicants respectfully request that the Examiner allow the Applicants to shift the invention notwithstanding the previous restriction. It is clear that the preamble, apparently being used to limit the claims in the prior restriction requirement, is the source of problems in the prosecution. Claims 32-36 are directed to a method of expressing the chain shortening enzyme in a plant cell. MPEP 819.01 states that the Examiner may allow such a shift where the shift results in no additional work or expense, and particularly where the shift reduces work as by simplifying the issues. Based on the prior art searching already performed, these claims are believed free of the prior art, moreover, it is plain that they remove the enablement issue from the case because they no longer state a preamble of improving vanillin production or the like. These claims are believed to be allowable as they overcome the enablement issue and are largely directed to the same invention as the steps of the elected claims. As the examiner has noted, they are broader with respect to the plants covered, and that scope is commensurate with the teachings of the specification and the skill in the art.

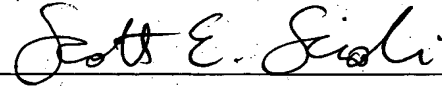
### **Conclusion**

The claims are in condition for allowance. Favorable reconsideration and a notice to that effect are earnestly requested. The Examiner is invited to contact the Applicants' below signed representative to resolve any outstanding minor issues prior to allowance. The representative's contact number is 215-557-5986 during normal working hours.

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**PATENT**

Respectfully submitted,

A handwritten signature in cursive script, reading "Scott E. Scioli", written over a horizontal line.

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